UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,104	01/27/2004	Woonza M. Rhee	113129.403C5	2188

41551 7590 11/25/2009

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVENUE, SUITE 5400
SEATTLE, WA 98104-7092

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,104	RHEE ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16,19-22,25-47,50,53-56 and 59-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16,19-22,25-47,50,53-56 and 59-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/17/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of IDS filed 9/17/09, amendments and remarks filed 8/10/09. Claim 15 is canceled. Claims 1, 14, 35, 70 and 73 are amended. Claims 1-14, 16, 19-22, 25-47, 50, 53-56 and 59-81 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-14, 16, 19, 20, 25, 29, 31, 35, 36-47, 50, 53, 54, 59, 61, 70 and 72 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rhee et al. (US 5,162,430) for reasons of record with modification to address the amendment to the claims.

3. Claims 1, 35 and 73 have been amended to recite "synthetic polylysine" instead of the synthetic polypeptide. The first cross-linkable component can also be poly(alkylene oxide) having m nucleophilic group where each nucleophilic group is amino or thiol. Claims 14, 70 and 72 now limit the first cross-linkable component to poly(alkylene oxide). The examiner notes that collagen-PEG having lysines meet the limitation of poly(alkylene oxide) having amino nucleophilic groups.

4. Rhee repairs tissues such as nose, ear, knee, larynx, tracheal rings; or replace tendon, ligament and blood vessel tissue by applying a mixture of collagen -dPEG (column 12, lines 49-

61). The PEG used in Rhee can also be activated as succinimidyl monomethylpolyethylene glycol (column 9, lines 1-6) and the succinimidyl ester PEG is capable of reacting with free amino groups as it does with the lysine residues of collagen (column 9, lines 6-10). The collagen-dPEG having lysines meets the limitation of poly(alkylene oxide) having amino nucleophilic groups of claims 1, 35 and 73 while the succinimidyl activated PEG meets the limitations of second precursors having different groups, nucleophilic and electrophilic groups as required by claims 1-13, 16, 19, 20, 25, 29, 35-47, 50, 53, 54, 59 and 63. The poly(alkylene oxide) of the collagen-dPEG containing lysine meets the limitation of the first cross-linkable component of claims 14, 70 and 72. The reaction of the activated PEG and the collagen appears to occur at about pH of 7 (column 9, line 60) meeting claims 27, 31 and 61. Rhee contemplates using molar excess of the activated PEG (column 10, line 2) meeting claims 33, 34, 67 and 68. Rhee contemplates an embodiment in which the mixture can be administered to the site before cross-linking is completed (column 7, lines 60-67; column 11, lines 60-64) meeting the requirement that claims 1, 35 and 73 (under 35 USC 103). While Rhee does not specifically state that the two solutions are separately applied, the two solutions are mixed and applied and polymerization and cross-linked in situ. Rhee teaches that the composition is administered to augment or repair soft or hard tissue (column 6, lines 28-46) meeting the methods of the claims.

5. Rhee teaches collagen that is chemically conjugated to PEG and since collagen is rich in amino acids such as lysine, proline, hydroxylysine and hydroxyproline; and since those amino acids most likely present on the collagen are the lysine, proline, hydroxylysine and hydroxyproline, Rhee's poly(alkylene oxide) contains amino functional groups. The succinimidyl meets claims 19 and 20. Cross-linking of the first and second precursor molecules

takes place in situ meeting the method steps of claims 1-5 and the nucleophilic and electrophilic groups on the first and second precursor meet claims 6-16. Therefore, the claims are met.

6. In the alternate, while Rhee teaches that cross-linking takes place in situ. But, if the order of the method steps differs, changes in the sequence of adding ingredients is not patentable over the method steps of Rhee and selection of any order of performing process steps is prima facie obvious in the absence of unexpected results. Therefore, taking the teachings of Rhee, one having ordinary skill in the art at the time the invention was made would follow the method steps of Rhee to apply the cross-linking precursors to the desired site where polymerization will take place to effect the expected augmentation of the tissue.

Response to Arguments

7. Applicant's arguments filed 8/10/09 have been fully considered but they are not persuasive.

8. Applicant argues that the amendment to claims 1, 35 and 73 reciting synthetic polylysine overcomes the Rhee reference because Rhee does not teach synthetic polylysine.

9. The examiner disagrees because while Rhee does not teach synthetic polylysine, the collagen-PEG having lysine groups meet the limitation of poly(alkylene oxide) having amino nucleophilic groups. Therefore, the designated claims are anticipated or rendered obvious by Rhee.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-14, 16, 19-22, 25-47, 50, 53-56 and 59-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee et al. (US 5,162,430) in view of Jiang et al. (US 5,505,952).

13. Claims 1, 35 and 73 have been amended to recite ""synthetic polypeptide or poly(alkylene oxide)." The first cross-linkable component can also be poly(alkylene oxide) having m nucleophilic group where each nucleophilic group is amino or thiol. Claims 14, 70 and 72 now limit the first cross-linkable component to poly(alkylene oxide). The examiner notes that collagen-PEG having lysines meet the limitation of poly(alkylene oxide) having amino nucleophilic groups.

14. Rhee has been described above to anticipate or render obvious claims 1-14, 16, 19, 20, 25, 29, 31, 35, 36-47, 50, 53, 54, 59, 61, 70 and 72. The collagen-dPEG having lysines meets the limitation of poly(alkylene oxide) having amino nucleophilic groups of claims 1, 35 and 73 while the succinimidyl activated PEG meets the limitations of second precursors having different groups, nucleophilic and electrophilic groups as required by claims 1-13, 16, 19, 20, 25, 29, 35-

47, 50, 53, 54, 59 and 63. The poly(alkylene oxide) of the collagen-dPEG containing lysine meets the limitation of the first cross-linkable component of claims 14, 70 and 72.. The reaction of the activated PEG and the collagen appears to occur at about pH of 7 (column 9, line 60) meeting claims 27, 31, 61 and 65. The concentrations/amounts recited in claims 26, 28, 30, 32, 60, 62, 64 and 66 would not patentably distinguish the claimed invention over the prior art in the absence of factual showing. Rhee contemplates using molar excess of the activated PEG (column 10, line 2) meeting claims 33, 34, 67 and 68. Rhee contemplates an embodiment in which the mixture can be administered to the site before cross-linking is completed (column 7, lines 60-67; column 11, lines 60-64) meeting the requirement that claims 1, 35 and 73. The two solutions in Rhee are mixed and applied and polymerization and cross-linked in situ. Rhee teaches that the composition is administered to augment or repair soft or hard tissue (column 6, lines 28-46) meeting the methods of the claims.

15. Rhee teaches collagen that is chemically conjugated to PEG and since collagen is rich in amino acids such as lysine, proline, hydroxylysine and hydroxyproline; and since those amino acids most likely present on the collagen are the lysine, proline, hydroxylysine and hydroxyproline , Rhee's poly(alkylene oxide) contains amino functional groups. The succinimidyl meets claims 19 and 20. Cross-linking of the first and second precursor molecules takes place in situ meeting the method steps of claims 1-5 and the nucleophilic and electrophilic group on the first and second precursor meet claims 6-14 and 16.

16. However, while the amine groups on collagen are primarily lysine, proline, hydroxylysine and hydroxyproline, Rhee does not state that the nucleophilic groups could be thiols. But compositions containing polyamino acid polymers such as polylysine and those having

methionine and cysteine have been shown in the prior art to be used to promote tissue repair or tissue growth according to Jiang at column 2, lines 54-64 and Example 1. The presence of methionine or cysteine meets claims 21, 22, 55, 5 and 78. Therefore, taking the teachings of the references together, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that combining the activated succinimidyl PEG with the polylysine polymer would lead to reaction of the ester functionality of the activated PEG and the amino group of the lysine which when administered to the tissue site would cross-link and act to augment the tissue. One of ordinary skill in the art at the time the invention was made would have reasonable expectation of success to augment soft tissue by administering the individual composition to the tissue site requiring augmentation in order for the two compositions to advantageously polymerize at the sites needing augmentation.

Response to Arguments

17. Applicant's arguments filed 8/10/09 as it relates to the current rejections have been fully considered but they are not persuasive.

18. Applicant argues because claims 1, 35 and 73 have been amended to recite polylysine, Rhee cannot anticipate or render obvious claims 1, 35 and 73 and therefore, cannot render obvious the claims dependent from claim 1, 35 and 73.

19. The examiner disagrees because as described above, while Rhee does not teach synthetic polylysine, the collagen-PEG having lysine groups meet the limitation of poly(alkylene oxide) having amino nucleophilic groups. Therefore, claims 1, 35 and 73 are anticipated or rendered obvious by Rhee and the claims dependent therefrom.

20. Applicant argues that Jiang is limited to cross-linking polyamino acid with small molecules as opposed to polymers.

21. But, Jiang is relied upon for using polyamino acid polymers to promote tissue repair. Secondly, as it regards the argument that Jiang is limited to cross-linking polyamino acid with small molecules as opposed to polymers, it is noted that the claims are not directed to binding polymers to the polyamino acids. Therefore, the designated claims are anticipated or rendered obvious.

22. Co-Owned US 6,534,591: The examiner thanks the applicant for bringing to the examiners attention US 6,534,591 having similar composition issued, which composition is used in the methods of the examined claims. But, each case proceeds independently and based on the facts in the case.

23. No claim is allowed.

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

25. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618